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EXAMINER	
KAUSHAL, SUMESH	
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1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,724	JACOBS ET AL.	
	Examiner	Art Unit	
	Sumesh Kaushal	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on 04/01/08 has been acknowledged and fully considered. In view of new grounds of rejections the following office action has been issued.

Claims 6-27 are pending and are examined in this office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

In view of applicants remarks the finally of the earlier office action is withdrawn. In addition the written description rejection(s) (claims 21-28) under 35 USC 112(1) and indefinite rejection (clams 21-28) under 35 UCS 112(2) are also withdrawn.

Claim Rejections - 35 USC § 112

Claims 6-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for protecting a mammal against *Streptococcus equi* infection by submucosal injection of a live attenuated *Streptococcus equi* strain (TW980), does not reasonably provide enablement for a method for protecting a mammal against all bacterial infection by sub mucosal injection of any live bacterial vaccines as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Nature of invention

The instant invention relates to administration of any live attenuated bacterial vaccine(s) by submucosal injection.

Breadth of Claims and Guidance Provided in the Specification

The scope of the instant invention as claimed encompasses a method of administering a live attenuated bacterial vaccine (any bacteria) to a mammal by injecting the vaccine into submucosal layer of a mammal. The scope of invention as claimed further encompasses a method for reducing the amount of adverse reaction in a mammal at injection site of live attenuated bacterial vaccine (any bacteria) by

administering the vaccine submucosally. In addition the scope of invention as claimed encompasses a method for systemic application of live attenuated bacteria to a mammal wherein the live attenuated bacteria is administered submucosally.

The scope of the invention as claimed encompasses the use of any and all attenuated bacterial vaccines. However, the instant specification as filed only discloses the use of ***Streptococcus equi* attenuated strains** (TW 928 and TW928/sls), which are deletion mutant vaccine strains (spec. page 7, example-1). Besides TW 928 (*Streptococcus equi)* the instant specification fails to disclose any live attenuated vaccine obtained from any other bacterial strain.

The specification fails to disclose any live attenuated vaccine obtained from *Actinobacillus equili, A. pleuropneumoniae, Actinomyces pyoyenes, Botdetella bronchiseptica, Brucella abortus, Clostridium perfringens, Corynebacterium bovis, C pseudotuberculosis, Erysipelotrix rhusioipathiae, Escherichia coli, Haemophilus parasuis, Leptospira canicola, L. hardjo, L icterohaemorrhagiae, L. poriona, Mycobacterium bovis, Mycoplasma bovis, M. hyopneumoniae, Noccatdia asteroides, Pasteurella haemolytica, P. multocida, Pseudomonas mallei, Rhodococcus equi, Salmonella cholerasuis, S. dublin, S. typimurium, Serpulina hyodysenteriae, Staphylococcus aureus, Streptococcus agalactiae, St. pneumoniae, St.suis, or St. uberis* explicitly or implicitly as putatively claimed herein.

The invention as claimed requires the use a product designated as Vaccine (which prevents the infection caused by a pathogen of interest). By definition the Vaccine is "Suspensions of killed or attenuated microorganisms (bacteria, viruses, fungi, protozoa, or rickettsiae), antigenic proteins derived from them, or synthetic constructs, administered for the prevention, amelioration, or treatment of infectious and other diseases" (see *http://www.ncbi.nlm.nih.gov/sites/entrez?db=mesh* MESH term Vaccine). Therefore, in view of fact that Vaccine is functional product that provides immune-protection against designated pathogens, it is unclear who one skilled in the art would practice the invention as claimed, when the specification as filed fail to disclosed the required vaccines. Furthermore in view of limited amount applicant's disclosure, it is unclear that the vaccines as claimed herein are able to provide immune protection (upon challenge) in any and all mammals. Thus it would require extensive and undue amount of

experimentation to practice the invention as claimed, which would requires making and testing the claimed vaccines in any and all mammals.

State Of Art And Predictability

The state of the art at the time of filing teaches that in spite of many achievements and the many attractive aspects of the attenuated bacterial vaccine technology, the intense worldwide efforts to develop further live bacterial vaccines are slow to come of age. This is mainly because it has proven very difficult to achieve the desired balance between safety and immunogenicity of candidate vaccine strains and stimulate strong mucosal and systemic immune responses, while avoiding unwanted side effects. Furthermore, the lack of relevant animal models allowing the prediction of the clinical outcome of candidate live oral vaccines during preclinical evaluation has certainly contributed to the observed high failure rate (see Frey, Vaccine, 25:5598-5605, 2007; Galen et al, Trends in Microbiology 9(8):372-376, 2001; Detmer et al, Microb Cell Fact. 23(5):1-12, 2006, Curtiss R. J. Clin. Invest. 110(8):1061-1066, 2002, Tiball et al Vaccine 19:4175-4184, 2001).

The development of a bacterial vaccine is considered highly unpredictable because the safety and efficacy of the vaccine is dependent upon the way the bacterial antigens are presented to the host and the sate of the host immune response it self. Furthermore several safety concerns of the live bacterial vaccine strain have been raised. Before using pathogenic bacteria for vaccination purposes, its pathogenicity must be weakened via attenuation. Attenuation usually involves deletion of essential virulence factors or mutation of genes encoding metabolic enzymes whose function is essential for survival outside the laboratory. Inactivation of a metabolic gene has the advantage that the bacteria still express virulence determinants important to elicit a protective immune response. Appropriate stable auxotrophic strains are usually not able to replicate in the human body and can safely be used even in immune compromised individuals. Defined deletions of at least two metabolic essential genes are usually used and decrease the probability of reversion to virulence (see Detmer et al, Microb Cell Fact. 23(5):1-12, 2006, ref of record).

Furthermore, the efficiency of any live bacterial vaccine hinges on its ability to present sufficient foreign antigen to the host immune system to initiate the desired protective immune response(s). However, synthesis of sufficient levels of heterologous antigen can result in an increase in metabolic burden with an accompanying decrease in the fitness of the live vector, which can ultimately lower desired immune responses to both live vector and heterologous antigen (see Galen et al, Trends in Microbiology 9(8):372-376, 2001).

In addition the state of attenuated bacterial vaccine art teaches was such that a rational approach to design a live attenuated bacterial vaccine involves genetic modification of the bacterial pathogen to make the pathogen less virulent while maintaining the stability of protective antigen expression that provides immune protection. The attenuation should be an inherent property of the bacterial vaccine and not be dependent on fully functional host defenses and immune response capabilities. (see Curtiss R. J. Clin. Invest. 110(8):1061-1066, 2002). The attenuation of a bacterium requires the modification of specific bacterial genes that render the bacterial strain non-virulent. For example, inactivation of PhoP/phoq regularoty system in S. typhi results in strains, which are suitably attenuated for use as vaccines (Tiball et al Vaccine 19:4175-4184, 2001, *ref of record*, see page 4177 sec 3.1).

Furthermore, the development of live attenuated bacterial vaccine has not been always predictable. For example, (i) development of a live attenuated *Shigella* vaccine that is sufficiently attenuated to be non-reactive yet adequately invasive to be highly immunogenic took 30 years in making, since it required substantial understanding of molecular genetic basis of virulence of *Shingella* (Curtiss page 1063, col.2). Therefore attaining the ultimate goal of vaccines that are safe and efficacious in humans can be both advanced and hindered by studies in animal systems. For example, (ii) the use of *S. typhimurium* in mice as a surrogate for *S. typhi* in humans has many real advantages. On the other hand, the disease caused by *S. typhimurium* in mice is not exactly the same as that caused by *S. typhi* infection in humans. To make matters worse, most scientists rely on mice that are inbred rather than outbred and that possess unique susceptibility to *S. typhimurium* infection. Similarly, use of outbred mice to

evaluate candidate recombinant attenuated *S. typhi* vaccines is likely very misleading. Evaluation of *S. typhi* attenuation has often employed intraperitoneal inoculation of outbred mice in the presence of hog gastric mucin. This assay seems to have worked very well for attenuated strains with *aro* mutations that preclude growth of the *S. typhi* but would lead one to believe that bacteria with *phoPQ* deletions are as virulent as wild-type bacteria, since their growth is not impeded and the mice succumb to endotoxic shock after growth of the *S. typhi* strain. It is also well known that *S. typhi* is unable to survive in murine macrophages of diverse types, and therefore the immunogenicity of *S. typhi* constructs after intranasal inoculation into mice is probably no different from that achieved by a diversity of pathogens that are unable to cause lethal infection in mice regardless of whether attenuating mutations are present. The development of strains of mice with enhanced susceptibility to *S. typhi* might overcome these problems. In this regard, the recent generation of transgenic mice with a receptor allowing *L. monocytogenes* infection via oral inoculation might provide a better model for development of recombinant attenuated *L. monocytogenes* vaccines for humans. Work toward development of improved *M. tuberculosis*–derived recombinant vaccines necessitates the discovery of attenuated *M. tuberculosis* strains unable to establish latent infections. Nevertheless, results from tests of vaccine candidates in mice or guinea pigs probably will not be reflective of responses in humans. Therefore, more studies on these various vaccine candidates must be conducted with human volunteers (see Curtiss R. J. Clin. Invest. 110(8):1061-1066, 2002).

Considering the undue amount of experimentation required to practice the invention as claimed, the specification fails to provide any guidance regarding how to make and use the live attenuated bacterial vaccines selected from the above-mentioned species (see claims 7, 11, 12 and 20), without further undue amount of experimentation. For example, the specification fails to disclose what are the bacterial regulatory systems in these bacteria (as claimed), mutation of which would result in the making of a live attenuated bacterial strain that would provide immune protection in mammals against any specific bacterial infection. The state of the art clearly teaches that understanding of regulatory pathways that affect bacterial virulence and protective antigens that

provides long-term immune protection are consider germane to the development of a live attenuated bacterial vaccine.

The USPTO does not have laboratory facilities to test if an invention will function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raised and discussed based on the state of knowledge pertinent to an art at the time of the invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of skill.

The disclosure "shall inform how to use, not how to find out how to use for themselves." See In re Gardner 475 F.2d 1389, 177 USPQ 396 (CCPA 1973). It is noted that patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable (*See Brenner v. Manson , 383 U.S. 519, 536, 148 USPQ 689, 696 (1966), Stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion"*) Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

In instant case to practice the invention as claimed one would require a live attenuated vaccine on hand. However the specification fails to provide any guidance regarding how make a live attenuated vaccine for all bacterial strains (other than *Streptococcus equi* attenuated strains TW928). At issue, under the enablement requirement of 35 U.S.C. 1 12, first paragraph is whether, given the Wands-factors, the experimentation was undue or unreasonable under the circumstances.
"Experimentation must not require ingenuity beyond that to be expected of one of ordinary skill in the art." See Fields v. Conover, 443 F.2d 1386, 170 USPQ 276 (CCPA 1970).

In addition, sub mucosal injection of any live attenuated bacterial strain (virulent) as vaccine is not considered routine in the art and without sufficient guidance to a specific bacterial strain and vaccination outcome base upon the immune protection the

experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir,1988). The amount of undue experimentation required would include sub mucosal injection of any live attenuated bacterial strains (as claimed) and evaluation of vaccine efficacy in order to provide immune protection. It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See Ex parte Singh, 17 USPQ2d 1714 (BPAI 1991). Therefore, one skill in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed.

RESPONSE TO ARGUMENTS (ENABLEMENT)

Regarding the enablement issues associated with the use of "live attenuated vaccines", the applicant argues that applicant's discovery is not limited to any specific live attenuated vaccine but is generally applicable to all live attenuated vaccines, independent of the bacterial strain or method of attenuation. The applicant argues that it is mere routine and if any is not undue experimentation to practice the invention as claimed. Regarding the enablement analysis in view of Wand's factors the applicant furhter argues that 1) Appellant's specification identifies a wide range of example live bacteria that are generally suitable for use with the invention. 2) The specification provides working examples that includes two different bacterial strains. 3) That in view of the state of the art one can easily make the vaccines required especially in view of evidence provided in table-I.

However the applicant's arguments are found not persuasive. Even though applicant asserts that in view references disclosed in Table-I the invention as claimed is fully enabled, the argument has been found not fully persuasive because the scope of invention as claimed is much broader than the limited number of vaccines cited in table-I. Furthermore each vaccine disclose in the table-I is host specific, whereas the scope of invention as claimed encompasses the use of any live bacterial attenuated vaccine for any mammal. The office has provided clear evidence that the efficacy of vaccine could be best judged in the context of pathogen/host etiology (see Curtiss R. J. Clin. Invest. 110(8):1061-1066, 2002, that explain unpredictability associated with the use of test

candidate vaccines in mice or guinea pigs that probably will not be reflective of responses in humans). Furthermore, impossibility of determining, from reading of specification and record, number of mutant strains of original S. typhi and hyperconjugant strains of genetically engineered hybrid that are originally formed in each experiment, nor what amount of time, effort, and level of skill is needed to isolate single strains which can then be cloned to yield useful vaccines, supports conclusion that practice of invention would require undue experimentation. Ex parte Formal, et al., 230 USPQ 546 (Bd. Pat. App. & Int. 1986)

The USPTO does not have laboratory facilities to test if an invention will function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raised and discussed based on the state of knowledge pertinent to an art at the time of the invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of skill.

Even description of several newly discovered strains of bacteria having one particularly desirable metabolic property in terms of conventionally measured culture characteristics and number of metabolic and physiological properties does not enable one of ordinary skill in relevant art to independently discover additional strains having same specific, desirable metabolic property, i.e., production of particular antibiotic; in other words, verbal description of new species does not enable one of ordinary skill in relevant art to obtain strains of that species over and above specific strains made available through deposit in recognized culture depositor. Ex parte Jackson, Theriault, Sinclair, Fager, and Karwowski, 217 USPQ 804 (Bd. Pat. App. & Int. 1982)

Furthermore, determination of what constitutes undue experimentation in given case requires application of standard of reasonableness, having due regard for nature of invention and state of art; test is not merely quantitative, since considerable amount of experimentation is permissible, if it is merely routine, or if specification in question provides reasonable amount of guidance with respect to direction in which experimentation should proceed to enable determination of how to practice desired embodiment of invention claimed. Ex parte Jackson, Theriault, Sinclair, Fager, and Karwowski, 217 USPQ 804 (Bd. Pat. App. & Int. 1982). In the instant case the

applicants disclosure is only limed to Strep equi (TW928) see example-1. The example 2 and 3 (Spec. pages 8-9) are only limited to wild-type bacterial strains of Strep. zooepidemicus and Actinomyces pyogenes, which doses not constitute a live attenuated bacterial vaccine (capable of providing immune protection and not infection).

Since the submucosal injection of any live attenuated bacterial strain as vaccine is not considered routine in the art and without sufficient guidance to a specific bacterial strain and vaccination outcome base upon the immune protection the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir,1988). It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See Ex parte Singh, 17 USPQ2d 1714 (BPAI 1991). Therefore, one skill in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6, 9 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Walker (Infection and Immunity. 31(1):61-70, 1981).

The scope of invention as claimed herein encompasses a method for submucosal injection of a live attenuated bacterial vaccine to mammal.

Walker teaches submucosal injection of S.mutans in monkeys which results in high titers of circulating antibodies (page 61, col.1, para 1-2). The cited art further teaches the use of dried live S.mutans cells as oral vaccine preparation (page 62, col.1, para.2). The cited art further teaches submucosal injection of vaccine preparation in the

mouth of experimental animals (page 62, col.2, para.1, para 2, lines 15-20). The cited art further teaches the comparison between the subcutaneous and submucosal immunization (pag 62, col.1 para.2; page 64 col.1 para.2). Thus given the broadest reasonable interpretation, the cited art clearly anticipates the invention as claimed.

"Anticipation does not require the actual creation or reduction to practice of the prior art subject matter; anticipation requires only an enabling disclosure." Schering Corp. v. Geneva Pharms., 339 F.3d 1373, 1380 (Fed. Cir. 2003) (citing In re Donohue, 766 F.2d 531,533 (Fed. Cir. 1985)). "In patent prosecution, the examiner is entitled to reject application claims as anticipated by a prior art patent without conducting an inquiry into whether or not that patent is enabled .... The applicant, however, can then overcome that rejection by proving that the relevant disclosures of the prior art patent are not enabled." Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1355 (Fed. Cir. 2003). Thus, "a presumption arises that both the claimed and unclaimed disclosures in a prior art patent are enabled" (id.).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7-8, 11-20, 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker (Inf. Imm. 31(1):61-70, 1981 as applied to claims 6, 9 and 21 above, and further in view of Stocker (US 4735801, 1988) and Hartford et al (EP 0786518 A1, 1997. ref of record on PTO1449).

The teaching of Walker has been described above. Even though Walker teaches Walker teaches submucosal injection of S.mutans in monkeys, the cited art fails to

teach that such a method could also be used in other mammals using variety of attenuated bacterial strains.

Stocker teaches live attenuated bacterial vaccine for Salmonella typhimurium wherein the attenuated vaccine can be used with a wide variety of domestic animals, as well as man. The cited art further teaches that included among domestic animals which are treated by vaccines today or could be treated, if susceptible to bacterial diseases, are chickens, cows, pigs, horses, goats, and sheep, to name the more important domestic animals (col.5, lines 30-35).

Harford teaches a method for protecting horses against *Streptococcus equi* by an oral administration of a live attenuated *Streptococcus equi TW928* strain (abstract, page 12, line 11-18).

Thus it would have been obvious to one ordinary skilled in the art at the time the instant invention was made to modify the invention of Walker with Stocker or Harford by substituting the S.mutans vaccines with other attenuated bacterial vaccine and in variety of domestic animals. One would have been motivated to do so to generate immune response against bacteria of interest in domestic animals. One would have been further motivated to inject the attenuated bacterial vaccine to bypass the mucosal barrier. One would have a reasonable expectation of success, since the use of oral vaccines been routine in the art at time the instant invention was made. Thus the invention as claimed is prima facie obvious in view of cited prior art of record.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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